

Department of Health and Ageing 2008-09 Regulatory Plan

Explanatory Note

The Department of Health and Ageing, like other Australian Government agencies which have responsibility for business regulation, is required to publish a regulatory plan on its web site early in each financial year.

The regulatory plan deals with changes within the Department's area of responsibility and contains information about:

- changes to business regulation which have occurred since the beginning of the previous financial year (1 July 2007 to 30 June 2008); and
- activities planned in the current financial year (1 July 2008 to 30 June 2009) which could lead to changes to business regulation.

What regulation does a regulatory plan cover?

A regulatory plan covers business regulation. This includes primary legislation, subordinate legislation, quasi-regulation or treaties that directly affect business, have a significant indirect effect on business, or restrict competition.

Quasi-regulation refers to rules or arrangements where governments influence businesses to comply, but which do not form part of explicit government regulation.

A regulatory plan does not include information about the following:

- regulations of a minor or machinery nature that do not substantially alter existing arrangements;
- regulations that involve consideration of specific government purchases;
- regulations of a state or self-governing territory that apply in a non-self governing territory; and
- anticipated activity about which it would be inappropriate to publish information on grounds of confidentiality.

In addition, there may be regulatory activities that have not been included in the regulatory plan because they could not be foreseen when the plan was prepared at the start of the financial year.

In view of these exclusions, users should not take a regulatory plan to be a comprehensive source of information on past or potential changes to business regulation.

How up to date is information in this regulatory plan?

This plan was last updated on 26 August 2008. Corrections were made on 19 November 2008

Past Regulatory Activity

Title	Aged Care Amendment (2008 Measures No.1) Act 2008 and Amendments to the Aged Care Principles 1997
Description of issue	Amendments to the <i>Aged Care Act 1997</i> and the Aged Care Principles to: implement changes to the fees paid by residents and the subsidies paid by the Government; broaden the eligibility for community care grants; make other technical amendments to the Act to improve its operation; and extend the application of aged care legislation to the Territory of Christmas Island and the Territory of Cocos (Keeling) Islands.
Date of effect	20 March 2008
Contact details	Debbie Miller Residential Program Management Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	Aged Care Amendment (Residential Care) Act 2007
Description of issue	Amendments to the <i>Aged Care Act 1997</i> to give effect to the implementation of the new aged care funding instrument.
Date of effect	Proclaimed to have effect from 20 March 2008
Contact details	Bevan Noble Funding Model Implementation Department of Health and Ageing Ph: (02) 6289 1578 Email: bevan.noble@health.gov.au

Title	Cosmetic Standard 2007
Description of issue	A new standard for cosmetics imported into or manufactured in Australia, including some products that had been previously regulated as therapeutic goods. Available at www.nicnas.gov.au
Date of effect	Made by the Parliamentary Secretary to the Minister for Health and Ageing on 17 September 2007
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au

Title	Health Care (Appropriation) Amendment Act 2008
Description of issue	This Act amended the <i>Health Care (Appropriation) Act 1998</i> to enable the payment of Health Care Grants to the states and territories in 2008-09.
Date of effect	25 June 2008
Contact details	Gail Yapp Assistant Secretary Acute Care Strategies Branch Department of Health and Ageing Phone: 02 6289 7601 Email: gail.yapp@health.gov.au

Title	Health Insurance Amendment Regulations 2008 (No. 1)
Description of issue	<p>The Regulations amended the <i>Health Insurance Regulations 1975</i> to give effect to a number of provisions incidental to the introduction of the Diagnostic Imaging Accreditation Scheme (the Scheme) which is enacted by the <i>Health Insurance Amendment (Diagnostic Imaging Accreditation) Act 2007</i>.</p> <p>As of 1 July 2008 the Scheme provides accreditation for all radiology services listed in the Diagnostic Imaging Services Table prescribed by the <i>Health Insurance (Diagnostic Imaging Services Table) Regulations 2007</i>, pursuant to subsection 4AA(1) of the <i>Health Insurance Act 1973</i>.</p> <p>Specifically, the Regulations:</p> <ol style="list-style-type: none"> (1) exempt diagnostic imaging services that are outside the scope of the Scheme (cardiac ultrasound and cardiac angiography; obstetric and gynaecological ultrasound; or nuclear medicine imaging); (2) prescribe the information about the accreditation that is required when applying for registration on the Diagnostic Imaging Register (maintained by Medicare Australia) when the premises or base is accredited at the time of the application; (3) and prescribe certain information about the accreditation status of diagnostic imaging premises and bases for mobile diagnostic imaging equipment to be recorded on the Diagnostic Imaging Register.
Date of effect	20 June 2008
Contact details	Mary Warner Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: mary.warner@health.gov.au

Title	Health Insurance (Diagnostic Imaging Accreditation) Determination 2008
Description of issue	<p>The Determination establishes a scheme under which diagnostic imaging practices can be accredited for diagnostic imaging procedures.</p> <p>The Determination remains in force until the end of 30 June 2010.</p>
Date of effect	16 May 2008
Contact details	Mary Warner Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: mary.warner@health.gov.au

Title	Health Insurance (Diagnostic Imaging Accreditation - Approved Accreditors) Determination 2008
Description of issue	<p>The Determination designates persons who will receive notices that are to be lodged by proprietors of diagnostic imaging practices who seek accreditation, and to approve the accreditors who are to receive and make decisions on applications by proprietors of diagnostic imaging practices seeking accreditation of their practices or bases for mobile services in accordance with the <i>Health Insurance (Diagnostic Imaging Accreditation) Determination 2008</i>.</p> <p>The Determination remains in force until the end of 30 June 2010.</p>
Date of effect	16 May 2008
Contact details	Mary Warner Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: mary.warner@health.gov.au

Title	Health Insurance (Permitted benefits - diagnostic imaging services) Determination 2008
Description of issue	<p>This Determination is made under section 23DZZIG of the <i>Health Insurance Act 1973</i>. Section 23DZZIG allows the Minister to determine by legislative instrument that a specified class of benefits, that would otherwise be unlawful under the Act, be permitted benefits.</p> <p>This Determination sets out certain benefits that are permitted, and the prescribed conditions under which they are permitted, in relation to diagnostic imaging.</p>
Date of effect	1 March 2008
Contact details	Mary Warner Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: mary.warner@health.gov.au

Title	Health Insurance (Eligible Collection Centres) Principles 2007
Description of issue	This replaces the 2005 Principles. The Principles regulate the allocation of Approved Collection Centres to pathology providers. A Regulation Impact Statement was prepared for these Principles.
Date of effect	1 July 2007
Contact details	Hilary Metcalf Diagnostic Services Branch Department of Health and Ageing Ph: (02) 6289 8657 Email: hilary.metcalf@health.gov.au

Title	Health Legislation Amendment Act 2007	
Description of Issue	This Act amended provisions which were unintentionally narrowed by the <i>National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007</i> . The amendments enabled current practice to continue through allowing pharmacists to continue to substitute other brands of other pharmaceutical items of the same drug that are flagged as being equivalent and interchangeable in the Schedule of Pharmaceutical Benefits. This Act also amended the <i>Private Health Insurance Act 2007</i> to ensure offence provisions applied to certain types of health insurance policies as intended.	
Date of effect	Received Royal Assent on 28 September 2007.	
Contact details	Gay Santiago Assistant Secretary (A/g) Policy and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7585 Email: gay.santiago@health.gov.au	Anne Kingdon Director Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 8283 Email: anne.kingdon@health.gov.au

Title	Health Emergency Management Branch – COAG Review of Hazardous Materials
Description of issue	The Council of Australian Governments (COAG) Review of Hazardous Biological Materials and its associated Report were considered and agreed by COAG on 13 April 2007. COAG agreed to the Report's recommendations which include the establishment of a national regulatory regimen to minimise the security risks posed by specific security-sensitive biological agents. The Department of Health and Ageing is responsible for implementing these recommendations. The new regimen has been enacted in Part 3 of the <i>National Health Security Act 2007</i> (the Act). The Act is available at this link: www.health.gov.au/ssba
Date of effect	28 September 2007
Contact details	Letitia Toms Laboratory Capacity and Regulation Section Health Emergency Management Branch Department of Health and Ageing Ph: (02) 6289 7477 Email: letitia.toms@health.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2008 (No. 1)
Description of issue	The Regulations increased new chemicals assessment fees and charges for the National Industrial Chemicals Notification and Assessment Scheme for 2008-09 by 3.9% (Consumer Price Index/Wage Cost Index). Available at www.nicnas.gov.au
Date of effect	1 July 2008
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007
Description of issue	The amendments enable the Minister to make standards for cosmetic products as a whole, that are imported into, or manufactured in, Australia. The second objective of the Act was the making of minor technical amendments to improve clarity and consistency within the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> . The Act provided amendments that delivered on the Government's commitment to reforming the regulation of cosmetics, providing more effective and streamlined regulation while also ensuring the continued safeguarding of health, safety and the environment. Available at www.nicnas.gov.au
Date of effect	Received Royal Assent on 20 August 2007; came into force 17 September 2007.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au

Title	Medical Indemnity (Prudential Supervision and Product Standards – Notice of Provision of Run-off Cover) Determination 2007
Description of issue	The Determination sets out the data to be provided to Medicare Australia by insurers in a written form in order to facilitate the management of the run-off cover scheme.
Date of effect	13 July 2007
Contact details	Paul Currall Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: paul.currall@health.gov.au

Title	Medical Indemnity (Run-off Cover Support Payment) Regulations 2008
Description of issue	To provide for the rate and payment arrangements for the Run-off Cover Support Payment, which is imposed on insurers under the <i>Medical Indemnity (Run-off Cover Support Payment) Act 2004</i> to fund the ongoing costs of the run-off cover indemnity scheme.
Date of effect	2 May 2008
Contact details	Paul Currall Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: paul.currall@health.gov.au

Title	National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007
Description of Issue	The Act gave effect to the new pricing arrangements associated with major reforms to Pharmaceutical Benefits Scheme which enable the benefits of competition to be captured where drugs have multiple brands.
Date of effect	Royal Assent was received on 28 June 2007; commenced 1 August 2007.
Contact	Gay Santiago Assistant Secretary (A/g) Policy and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7585 Email: gay.santiago@health.gov.au

Title	National Health Amendment (Pharmaceutical Benefits Scheme) Act 2008	
Description of issue	<p>The Act amended the <i>National Health Act 1953</i> to provide for:</p> <ul style="list-style-type: none"> • co-marketed brands – an amendment of section 84AE of the Act to expand the criteria used in determining whether brands of pharmaceutical items are co-marketed; • supply of pharmaceutical benefits to government officers working outside Australia couples living apart – to amend sections of the Act relating to safety net concession and pharmaceutical benefits entitlement cards issued to people who are either legally married or are in de facto relationships; • couples who live apart due to illness or infirmity to be considered as family for the purpose of entitlement to safety net concession and pharmaceutical benefits entitlement cards; • miscellaneous – amended the definitions of ‘combination item has a drug’ and ‘pharmaceutical item has a drug’ in accordance with proposed amendments in Schedule 1 of the Bill relating to co-marketed items. 	
Date of effect	Royal Assent was received on 25 June 2008; commenced 26 June 2008.	
Contact details	Diana MacDonell Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: diana.macdonell@health.gov.au	Gay Santiago Assistant Secretary (A/g) Policy and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7585 Email: gay.santiago@health.gov.au

Title	National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)	
Description of issue	Amendment of the pharmacy location rules to address shopping centre “backfilling” that was causing clustering of pharmacies in areas already well serviced by existing pharmacies.	
Date of effect	27 March 2007	
Contact details	David Pearson Pharmacy Access Section Community Pharmacy Branch Department of Health and Ageing Ph: (02) 6289 8984 Email: david.pearson@health.gov.au	

Title	Health Insurance (Permitted benefits – diagnostic imaging services) Determination 2008 and Health Insurance (Permitted benefits – pathology services) Determination 2008	
Description of issue	These determinations set out details relating to specific elements of the pathology and diagnostic imaging prohibited practices provisions of the <i>Health Insurance Act 1973</i> resulting from the <i>Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007</i> .	
Date of effect	March 2008	
Contact details	Hilary Metcalf Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 8657 Email: hilary.metcalf@health.gov.au	

Title	Private Health Insurance Legislation Amendment Act 2008
Description of issue	<p>The <i>Private Health Insurance Act 2007</i> was amended to require private health insurers to become companies within the meaning of the <i>Corporations Act 2001</i>. All private health insurers must be companies by 1 January 2010.</p> <p>Amendments to the <i>Australian Securities and Investments Commission Act 2001</i>, the <i>Corporations Act 2001</i>, the <i>Insurance Act 1973</i> and the <i>Insurance Contracts Act 1984</i> were also made so that the 'health-related business' of private health insurers is regulated by Private Health Insurance Administration Council (PHIAC) alone, rather than Australian Prudential Regulation Authority and PHIAC.</p>
Date of effect	25 June 2008
Contact details	Anne Kingdon Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: anne.kingdon@health.gov.au

Title	Therapeutic Goods Amendment (Poisons Standard) Act 2008
Description of issue	<p>This Act amended the <i>Therapeutic Goods Act 1989</i> to address the legal consequences arising from the decision of the Federal Court in <i>Roche Products v National Drugs and Poisons Schedule Committee</i> on 30 August 2007. The amendments were necessary to reinstate any scheduling decisions based on the Poisons Standard, and amendments made to it, that may have been repealed and became unenforceable because of the operation of the <i>Legislative Instruments Act 2003</i> (the LIA). The Act also puts beyond doubt that scheduling decisions made before the Roche decision are enforceable because they are deemed to have complied with the requirements of the LIA. Other consequential amendments were also implemented.</p>
Date of effect	20 March 2008
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au

Title	Therapeutic Goods Amendment Act 2007
Description of issue	<p>Amends section 9B of the <i>Therapeutic Goods Act 1989</i> to substitute the existing requirement for medical device sponsors to have their product entered in the Australian Register of Therapeutic Goods as "included" medical devices by 4 October 2007 with a requirement to lodge an application by 4 October 2007.</p>
Date of effect	3 October 2007
Contact details	Dr Graeme Harris Deputy Director Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8809 Email: graeme.harris@tga.gov.au

Planned Regulatory Activity

Title	Amendments to Private Health Insurance Rules 2007
Description of issue	Various amendments to the Rules are planned to update prostheses benefits, as required through the year.
Consultation opportunities	Prostheses List benefits are developed in consultation with industry and other stakeholders through Prostheses and Devices Committee processes.
Expected timetable	February 2009, August 2009
Contact details	Anne Kingdon Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: anne.kingdon@health.gov.au
Date last modified	23 July 2008

Title	Amendments to the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Charges) Regulations 1990
Description of issue	Amendments are required to be made to the <i>Therapeutic Goods Regulations 1990</i> and the <i>Therapeutic Goods (Charges) Regulations 1990</i> as a consequence of the amendments to be implemented by the Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008. The amendments include: <ul style="list-style-type: none"> • setting out dates when certain annual charges become payable; • clarification of requirements in relation to the low value turnover exemption from annual charges such as the making of an application for the exemption, deadlines for the making of an application and provision of relevant statements and information, lapsing of an application, the granting of an exemption, the cancellation of an exemption, application fee, the requirement relating to the provision of statements certified by an approved person in relation to an application for exemption, the obtaining of additional information or documents from applicants for an exemption or persons granted exemption, and merits review; and • other consequential and technical amendments.
Expected timetable	1 July 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au
Date last modified	July 2008

Title	Amendment to the Therapeutic Goods (Medical Devices) Regulations 2002
Description of issue	An amendment to the Regulations to exempt specific medical devices that are to be used for emergency purposes from the inclusion in the Australian Register of Therapeutic Goods. The exemption will be made under section 41HA of the <i>Therapeutic Goods Act 1989</i> . The exemption will be subject to conditions such as terms of supply and other requirements. These exemptions are required to be in place as soon as possible as they will form part of a stockpile of therapeutic goods to create a preparedness to deal with potential threat to public health.
Consultation opportunities	
Expected timetable	The amendments to the Regulations are to be implemented as soon as possible as some of the goods that form part of the stockpile will need to be replenished as soon as possible.
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au
Date last modified	July 2008

Title	Amendment to the Therapeutic Goods (Medical Devices) Regulations 2002
Description of issue	An amendment to the Regulations to implement the new regulatory framework for <i>In vitro</i> diagnostic (IVD) devices. Consequential amendments will also be required in relation to applicable fees and charges.
Consultation opportunities	This proposal has been agreed by the Australian Health Ministers' Conference and the Australian Health Ministers' Advisory Council. There has been ongoing consultation with stakeholders including industry, professional bodies and consumers since 2003. Extensive stakeholder consultation on draft IVD Rules for Trans-Tasman Joint Agency occurred in May/June 2007.
Expected timetable	Implementation was expected with the commencement of the joint regulatory scheme with New Zealand. Negotiations to establish an Australia New Zealand Therapeutic Products Authority were suspended in July 2007. The Government has agreed that the TGA progress the development of the IVD framework in an Australia-only context.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2008

Title	Amendment to Therapeutic Goods Act 1989 – definition of complementary medicines
Description of issue	Amend section 52F of the <i>Therapeutic Goods Act 1989</i> to expand definitions relating to complementary medicines. New definition would more clearly define the boundaries for regulation by providing objective criteria for determining eligibility for regulation as a complementary medicine. Allows for innovation otherwise precluded by the previous requirement to have a traditional use. Medicinal products determined <u>NOT</u> to be complementary medicines may still be regulated as Listed medicines.
Consultation opportunities	Consultation undertaken in the lead up to the establishment of the previously proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). However, given that the ANZTPA has now been indefinitely postponed, the Australian Government will now move to introduce these regulatory requirements within the Australian context.
Expected timetable	June 2009
Contact details	Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2008

Title	Amendments to the Therapeutic Goods Regulations 1990
Description of issue	<p>Following the postponed establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA), the following proposed amendments to the regulation of Listed medicines will be progressed:</p> <ul style="list-style-type: none"> • introduction of a new requirement for Listed medicines containing an ingredient of animal origin to require pre-clearance from the TGA prior to submission of an application to List a medicine on the Australian Register of Therapeutic Goods (ARTG); • changes to incorporate additional Certifications made by sponsors when Listing a medicine under subsection 26A(2) of the <i>Therapeutic Goods Act 1989</i> to incorporate additional certifications requiring: 1) the sponsor to hold product specifications and labels (draft or actual) for the medicine; and 2) that the sponsor holds data that demonstrates that the specifications attributed to the product by the manufacturer will continue to be met for the duration of the product's shelf life when stored under appropriate conditions nominated by the manufacturer; • the sponsor not to supply listed medicines after the expiry date of the goods; • mandate that sponsors only to include colouring agents in Listed medicines that are permitted by the TGA for products intended to be ingested; • introduction of a revised definition of 'herbal substance' to allow for a broader range of traditional medicines to be recognised. Additionally, to implement regulatory enhancements recommended by the <i>Expert Committee on Complementary Medicines in the Healthcare System</i>; • amend Schedule 7, Item 2(b) of the Regulations to 'is a herbal material, an oil obtained from a herbal material or an ingredient used in the manufacture of a Listed medicine, the sole therapeutic purpose of which is as a starting material for use by a TGA approved medicine manufacturer'; • amend Schedule 10, Part 2 and Items 2, 3 and 4 to replace 'excipient' with 'ingredient'; • to mandate the use of coded indications when entering the therapeutic purpose(s) for the medicine in an application to include a Listed medicine on the ARTG.
Consultation opportunities	On-going consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Governments intention to introduce legislation within the Australian context.
Expected timetable	June 2009
Contact details	Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2008

Title	Amendment to Therapeutic Goods Act 1989 - suspension of registered or listed therapeutic goods from the ARTG
Description of issue	Changes to the <i>Therapeutic Goods Act 1989</i> are required to allow for the suspension of registered and listed medicines from the Australian Register of Therapeutic Goods under certain circumstances. The ability to suspend would provide regulators with greater flexibility of regulatory response as currently regulators can only cancel a registration or listing.
Consultation opportunities	Consultation with key stakeholders was undertaken as part of the broader Australia New Zealand Therapeutic Products Authority process.
Expected timetable	Implementation anticipated in late 2009
Contact details	Mick O'Connor Executive Support Unit Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.oconnor@tga.gov.au
Date last modified	July 2008

Title	Amendment to Therapeutic Goods Regulations 1990 - Committees
Description of issue	Changes are required to the <i>Therapeutic Goods Regulations 1990</i> regarding membership, terms of reference and processes of TGA committees.
Consultation opportunities	The proposed committee changes were developed and consulted on as part of the broader Australia New Zealand Therapeutic Products Authority reforms.
Expected timetable	June 2009
Contact details	Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.oconnor@tga.gov.au
Date last modified	July 2008

Title	Amendment to Therapeutic Goods Regulations 1990 – Infringement Notices
Description of issue	Changes are required to the <i>Therapeutic Goods Regulations 1990</i> to implement an infringement notice scheme. This scheme was incorporated into the <i>Therapeutic Goods Act 1989</i> in 2006 but its implementation was delayed due to Australia New Zealand Therapeutic Products Authority (ANZTPA) reforms.
Consultation opportunities	Extensive stakeholder consultation has been undertaken, including as part of the broader ANZTPA reforms.
Expected timetable	June 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au
Date last modified	July 2008

Title	Development and implementation of a Trans-Tasman regulatory scheme for therapeutic products
Description of issue	<p>Therapeutic goods have a special exemption under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA seeks to lessen regulatory and trade barriers between Australia and New Zealand.</p> <p>To resolve the special exemption, which must be renewed each year, the Australian and New Zealand Government have agreed by means of a treaty to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) to harmonise therapeutic goods regulation between both countries.</p> <p>Negotiations to establish ANZTPA were postponed on 16 July 2007 when the New Zealand Government announced that it would not be proceeding with its enabling legislation. This was in recognition that New Zealand Government did not have sufficient support in the New Zealand Parliament to ensure the passage of its Bill at this time.</p>
Consultation opportunities	
Expected timetable	The Agreement between the Governments of Australia and New Zealand for the establishment of a Joint Scheme for the Regulation of Therapeutic Products remains in place and is able to be revisited at some future time.
Contact details	<p>Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au</p>
Date last modified	July 2008

Title	Amendment of Health Care (Appropriation) Act 1998
Description of issue	<p>There may be a requirement to amend the <i>Health Care (Appropriation) Act 1998</i> toward the end of 2008-09 to enable the payment of Health Care Grants to the states and territories in 2009-10 and beyond. However this depends on a decision yet to be made by the government on the reform of Commonwealth/state financing arrangements.</p> <p>It is possible that agreements reached on reformed Commonwealth/State financing arrangements as they relate to health will also require amendments to the <i>New Tax System (Goods & Services Tax) Act 1999</i> and the <i>National Health Act 1953</i>.</p>
Consultation opportunities	Consultations on the reform of Commonwealth/state financing arrangements are taking place under the auspices of the Australian government and the implications of reform are being worked through by various Council Of Australian Governments subcommittees.
Expected timetable	If it is decided that an amended <i>Health Care (Appropriation) Act 1998</i> will be the appropriation mechanism for health care grants in 2009-10 and beyond, the amendment need not take effect until the end of 2008-09 financial year.
Contact details	<p>Gail Yapp Assistant Secretary Acute Care Strategies Branch Acute Care Division Phone: 02 6289 7601 Email: gail.yapp@health.gov.au</p>
Date last modified	July 2008

Title	Health Legislation Amendment (Pharmaceutical Benefits Supply) Bill – relating to approval and entitlement of pharmacists and private hospitals to supply pharmaceutical benefits
Description of issue	To make minor, technical and consequential amendments identified during the development of the new pharmacy location rules.
Consultation opportunities	Ongoing consultation with Medicare Australia, the Pharmacy Guild of Australia and private hospital authorities.
Expected timetable	To be determined.
Contact details	David Pearson Community Pharmacy Branch Department of Health and Ageing Ph: (02) 6289 8984 Email: david.pearson@health.gov.au
Date last modified	3 July 2008

Title	Health Insurance Amendment Regulations 2008
Description of issue	To amend the <i>Health Insurance Regulations 1973</i> to set out details relating to specific elements of the pathology and diagnostic imaging prohibited practices provisions of the <i>Health Insurance Act 1973</i> .
Consultation opportunities	In December 2007, the Department circulated a discussion paper on the proposed content of the regulations to the relevant key professional bodies. The discussion paper was also published on the Department's website seeking comment from interested parties.
Estimated timetable	Proposed to be made in October 2008.
Contact details	Hilary Metcalf Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 8657 Email: hilary.metcalf@health.gov.au
Date last updated	August 2008

Title	Health Emergency Management – COAG Review of Hazardous Materials
Description of issue	<p>The Council of Australian Governments (COAG) Review of Hazardous Biological Materials and its associated Report were considered and agreed by COAG on 13 April 2007. COAG agreed to the Report's recommendations which include the establishment of a national regulatory regimen to minimise the security risks posed by specific security-sensitive biological agents (SSBA). The Department of Health and Ageing is responsible for implementing these recommendations. The new regimen has been enacted in Part 3 of the National Health Security Act 2007 (the Act).</p> <p>The SSBA regulatory scheme includes the following elements:</p> <ul style="list-style-type: none"> • establishment of a List of SSBA; • determination of Standards for SSBA; • the collection, and recording on a National Register of information about the nature and location of SSBA handled by entities/facilities in Australia; • restrictions in relation to the secure handling of SSBA; and • monitoring of compliance with Part 3 through an inspection regimen. <p>The List of SSBA is not a legislative instrument and will be made by the Minister.</p> <p>The SSBA are divided into 2 tiers; with Tier 1 agents being assessed by COAG as being more security sensitive. Following the establishment of an administrative unit within the Department of Health and Ageing, legislative instruments proposed to support the above elements are being developed. The handling of Tier 1 agents will be regulated from January 2009 and handling of Tier 2 agents will be regulated in 2010.</p> <p>On commencement of the regulatory scheme, entities that handle SSBA will be required to report their handlings to the Department and comply with the SSBA Standards which include standards relating to physical security, personnel security and transport.</p>
Consultation opportunities	<p>States and Territories and Australian Government agencies were consulted on development of the Act.</p> <p>An Implementation Advisory and Consultative Committee was established in January 2008 with representation from Australian government agencies, counter-terrorism and intelligence agencies. This is the primary mechanism for consultation and input to the development of the scheme. Specific and technical advice is provided by a Regulation and Standards Working Group comprising representatives from public health laboratories, animal health laboratories, a government regulator and the Department of Foreign Affairs and Trade. There have been two meetings of the above Committee and Working Group. Out of session meetings have occurred with border agencies. Other out of session meetings will also be held as appropriate.</p> <p>Consultations have also occurred with the Australian Federal Police, jurisdictional state and territory law enforcement agencies and counter-terrorism agencies. Public workshops held in late June and early July 2008 in six capital cities discussed the draft SSBA Standards. The draft is available for public comment until 1 August 2008. There will also be significant consultation, education and awareness activities undertaken in September 2008. The SSBA regulatory scheme roadshow will include an exposure draft of the proposed regulations, information on the new regulatory scheme and will raise awareness of security issues. More information is available at www.health.gov.au/ssba</p>
Expected timetable	List of SSBA, SSBA Standards and regulations will commence in January 2009.
Contact details	<p>Letitia Toms Laboratory Capacity and Regulation Section Health Emergency Management Branch Department of Health and Ageing Ph: (02) 6289 7477 Email: letitia.toms@health.gov.au</p>
Date last modified	14 July 2008

Title	Import, export and monitoring arrangements for controlled drug substances
Description of issue	The Office of Chemical Safety will review existing internal processes and documentation that support the import/export and monitoring framework for controlled drugs. It is expected that process will identify opportunities to streamline, update or clarify the processes and policies (including quasi-regulation) that underpin the import/export and monitoring of controlled drugs. It is also expected that this process will identify opportunities to streamline, update or clarify relevant parts of the <i>Customs (Prohibited Imports) Regulations 1956</i> and <i>Customs (Prohibited Exports) Regulations 1958</i> that relate to narcotic, psychotropic or precursor substances.
Consultation opportunities	Specific consultation mechanisms are yet to be determined and will depend on the nature and extent of any regulatory change that is contemplated. Consultation would include government, business and community representatives. Regulation Impact Statements would be developed where required.
Expected timetable	It is intended that an internal review of processes will be conducted in the first half of 2008-09 and a more formal arrangement to review and consult on potential regulatory changes may be initiated after that. A specific timetable is yet to be determined.
Contact details	George Thomas Treaties and Compliance Office of Chemical Safety Ph: (02) 6160 3250 Email: george.thomas@health.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment (Disinfectants) Bill 2009
Description of issue	<p>The amendments will provide for changes to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> to enable the transfer of responsibility of some chemicals in disinfectant products from the Therapeutic Goods Administration (TGA) to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).</p> <p>The Bill will present amendments that deliver on the Government's commitment to reforming the regulation of disinfectants, providing more effective and streamlined regulation while also ensuring the continued safeguarding of health, safety and the environment.</p> <p>Will be made available at www.nicnas.gov.au A Regulation Impact Statement will be prepared.</p>
Consultation opportunities	Both NICNAS and the TGA are consulting widely with a broad range of stakeholders, including the disinfectants industry and its industry bodies, and worker and community representatives, on a set of reform options prepared by an independent consultant for NICNAS and the TGA.
Expected timetable	Implementation by December 2009, with date of introduction of Bill to Parliament to be determined.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Bill 2009
Description of issue	<p>Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program.</p> <p>Recommendations that may result in adjustments to regulation include the identification of downstream use information, streamlining the secondary notification process, the development of new assessment products, the development of a new categorisation and prioritisation process for existing chemicals and a scoping study on monitoring of adverse. At the same time, various minor, technical changes will be made to improve the efficiency of NICNAS regulatory processes.</p> <p>A Regulation Impact Statement will form part of the process.</p>
Consultation opportunities	An Implementation Steering Group comprising government, industry and community representatives, along with Technical Working Parties, is guiding the implementation of the recommendations. Consultation with stakeholders will continue in accordance with the protocols and principles in the NICNAS Community Engagement Charter in 2008-09.
Expected timetable	It is intended that implementation will occur in stages over the next several years, with a specific timetable for legislative change yet to be determined.
Contact details	Matt Gredley Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2008
Description of issue	<p>A number of regulations are required for implementing outstanding Low Regulatory Concern Chemicals (LRCC) reforms.</p> <p>No specific Regulation Impact Statement (RIS) for regulations is required as it is covered in the RIS prepared for the LRCC amendment to the <i>Industrial Chemical (Notification and Assessment) Act 1989</i> (made by the <i>Industrial Chemical (Notification and Assessment) Amendment (Cosmetics) Act 2007</i>).</p>
Consultation opportunities	Consistent with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Community Engagement Charter, established consultative mechanisms will be used including the NICNAS Industry Government Consultative Committee and the Community Engagement Forum. In addition, public consultation on the proposed changes occurred in October 2006.
Expected timetable	December 2008
Contact details	Matt Gredley Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2009
Description of issue	Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. A Regulation Impact Statement will form part of the process.
Consultation opportunities	The implementation of the recommendations is being guided by an Implementation Steering Group comprising government, industry and community representatives, along with Technical Working Parties. Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation continuing in 2008-09.
Expected timetable	It is intended that modifications to the Regulations will occur as each requirement is developed in step with legislative changes, such as those for secondary notification processes, new assessment products, etc.
Contact details	Matt Gredley Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2009
Description of issue	The Regulations will increase New Chemical assessment fees and charges and registration fees for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2009-10. The exact percentage increase is yet to be determined. Office of Best Practice Regulation will be consulted on the need for a Regulation Impact Statement.
Consultation opportunities	Established consultative mechanisms will be used including the NICNAS Industry Government Consultative Committee.
Expected timetable	Expected to be 1 July 2009 for New Chemical assessment fees and charges and 1 September 2009 for registration fees.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2009
Description of issue	The Regulations will introduce conditions or restrictions to allow the controlled introduction of a chemical subject to section 106 of the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> . Office of Best Practice Regulation will be consulted on the need for a Regulation Impact Statement.
Consultation opportunities	Established consultative mechanisms will be used including the National Industrial Chemicals Notification and Assessment Scheme Industry Government Consultative Committee.
Expected timetable	April 2009
Contact details	Nick Walton Compliance and Reporting National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8807 Email: nick.walton@nicnas.gov.au
Date last modified	July 2008

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2009
Description of issue	Minor amendment of regulation 11C is required to clarify the conditions relating to the <i>Fuel Quality Standards Act 2000</i> . Office of Best Practice Regulation will be consulted on the need for a Regulation Impact Statement.
Consultation opportunities	Established consultative mechanisms will be used including the National Industrial Chemicals Notification and Assessment Scheme Industry Government Consultative Committee.
Expected timetable	April 2009
Contact details	Sneha Satya Existing Chemicals National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 Email: sneha.satya@nicnas.gov.au
Date last modified	July 2008

Title	Implementation of a new regulatory framework for human cellular and tissue therapies
Description of issue	A new regulatory framework for Human Cellular and Tissue Therapies (HCTs).
Consultation opportunities	There have been a number of public consultations with all States, Territories, Acute Care Division of the Department of Health and Ageing, New Zealand Ministry of Health and Medsafe, and key professional groups which have continued to further clarify the development of the proposed framework.
Expected timetable	Australian Health Ministers' Conference (AHMC) endorsement of Classes 2, 3 and 4 for the framework obtained in November 2006. Implementation was planned to coincide with the commencement of the Australia New Zealand Therapeutic Products Authority (ANZTPA), however negotiations to establish ANZTPA were suspended in July 2007. The Government has agreed that the TGA progress the implementation of the AHMC-endorsed HCT regulatory framework in an Australia-only context.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2008

Title	Implementation of a new framework for the regulation of Biologicals
Description of issue	Development of a separate regulatory scheme for Biologicals to include blood components, blood products and human cellular and tissue therapies (incorporating the Human Cellular and Tissue Therapies framework listed above).
Consultation opportunities	The Acute Care Division of the Department of Health and Ageing, the Jurisdictional Blood Committee, the National Blood Authority and New Zealand's Medsafe and Ministry of Health have been consulted.
Expected timetable	Implementation was scheduled to coincide with the commencement of the Australia New Zealand Therapeutic Products Authority. Due to the postponement of the joint agency this is being reviewed.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2008

Title	Implementation of a new regulatory framework for homoeopathic, medicines and related remedies which make therapeutic claims
Description of issue	<p>In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to implement regulations for homoeopathic medicines and related remedies making therapeutic claims, to ensure they meet appropriate standards of safety, quality and efficacy.</p> <p>The TGA has developed the regulatory framework for these medicines, within the context of the previously proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). However, given that the ANZTPA has now been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within the Australian context.</p>
Consultation opportunities	<p>Consultation (including a Regulation Impact Statement) took place in both Australia and New Zealand during May to August 2006. Ongoing consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Government's intention to introduce legislation within the Australian context.</p>
Expected timetable	June 2009
Contact details	<p>Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au</p>
Date last modified	July 2008

Title	Include new conditions of Listing for low risk (Listed) medicines
Description of issue	<p>The TGA is proposing to add additional conditions on the Listing of medicines to require:</p> <ul style="list-style-type: none"> • that the sponsor of the medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Australian Register of Therapeutic Goods; • the sponsor to keep records relating to the medicine necessary to 1) expedite recall if necessary of any batch of the listed medicine and 2) identify the manufacturer(s) of each batch of the medicine; • the sponsor to keep copies of relevant Goods Manufacturing Process agreements where any part of or step in the manufacture in Australia of the medicine is sub-contracted to a third party who is not the sponsor; • the sponsor to retain records of the distribution of the Listed medicine for a period of five years and shall provide the records or copies of the records to the TGA upon request; • the sponsor to report all reports of adverse reactions or similar experiences associated with the use or administration of the medicine to be notified to the TGA's Adverse Drug Reaction Unit as soon as practicable after the sponsor becomes aware of those reports; and • the sponsor to notify the TGA of any regulatory action taken against the goods relating to its quality, safety or efficacy by an overseas jurisdiction when the goods are supplied overseas.
Consultation opportunities	Ongoing consultation with key stakeholders was undertaken as part of the broader Australia New Zealand Therapeutic Products Authority (ANZTPA) process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Government's intention to introduce legislation within the Australian context.
Expected timetable	June 2009
Contact details	Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2008

Title	Implementation of a legally enforceable standard for the levels and kinds of evidence to support indications and claims for Listed complementary medicines
Description of issue	<p>In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to prescribe in the <i>Therapeutic Goods Regulations 1990</i>, the TGA's <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims for Listed Medicines</i> (the Guidelines) as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines.</p> <p>The TGA has reviewed the existing Guidelines with the intent of developing an Order to provide legislative underpinning as part of the move to the Australia New Zealand Therapeutic Products Authority (ANZTPA). However, given that the ANZTPA has been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within existing Australian legislation.</p>
Consultation opportunities	Ongoing consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Government's intention to introduce legislation within the Australian context.
Expected timetable	June 2009
Contact details	<p>Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au</p>
Date last modified	July 2008

Title	Implementation of legally enforceable quality standards for ingredients in complementary medicines.
Description of issue	<p>In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to introduce legally enforceable quality standards for ingredients in complementary medicines.</p> <p>As part of the proposed move to the Australia New Zealand Therapeutic Products Authority (ANZTPA), the TGA had developed an Order to provide legal underpinning for the quality standards to apply to new complementary medicine substances and those substances which currently have quality parameters outlined in TGA Compositional Guidelines where there is no mandatory standard.</p> <p>Whilst the TGA has undertaken this work within the context of the proposed ANZTPA, given that the ANZTPA has now been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within existing Australian legislation.</p>
Consultation opportunities	On-going consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Government's intention to introduce legislation within the Australian context.
Expected timetable	June 2009
Contact details	<p>Prof David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au</p>
Date last modified	July 2008

Title	Legislative change to implement a revised framework for the advertising of therapeutic products
Description of issue	<p>Changes to the <i>Therapeutic Goods Act 1989</i> and the <i>Therapeutic Goods Regulations 1990</i> are required to improve the co-regulatory scheme for the advertising of therapeutic products</p> <p>It was planned that a revised advertising co-regulatory model would be implemented with the trans-Tasman therapeutic products regulatory scheme. With the decision in July 2007 to postpone negotiations on the establishment of the scheme, there is still a need to finalise advertising arrangements in an Australian-only context.</p>
Consultation opportunities	<p>The proposed trans-Tasman advertising co-regulatory model was substantially based on the report of the Interim Advertising Council (IAC), which included broad membership of all key stakeholder groups. Stakeholders also participated extensively in the consultation process in both Australia and New Zealand on issues that were considered by the IAC.</p> <p>Face-to-face stakeholder meetings were held in February 2007 following the release of the draft Australia New Zealand Therapeutic Products Regulatory Scheme Advertising legislation. Additionally, an Advertising Implementation Steering Group had been established to guide the implementation of the operational aspects of the new regulatory model for the advertising of therapeutic products in Australia and New Zealand. It comprised of similar membership to the IAC.</p>
Expected timetable	<p>It was planned that a revised advertising co-regulatory model would be implemented with the trans-Tasman therapeutic products regulatory scheme. Due to the decision in July 2007 to postpone negotiations on the establishment of the trans-Tasman therapeutic products regulatory scheme, work to adapt the joint scheme provisions for an advertising co-regulatory framework in Australia is under review.</p>
Contact details	<p>Pio Cesarin Office of Non Prescriptions Medicines Therapeutic Goods Administration Ph: (02) 6232 8660 Email: pio.cesarin@tga.gov.au</p>
Date last modified	July 2008

Title	Legislative change to implement a revised scheduling framework
Description of issue	Changes are required to the <i>Therapeutic Goods Act 1989</i> and the <i>Therapeutic Goods Regulations 1990</i> to implement one of the recommendations of the <i>National Competition Policy Review of Drugs and Poisons and Controlled Substances Legislation</i> (the 'Galbally Review'), namely that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – the Medicines Scheduling Committee and the Chemicals Scheduling Committee.
Consultation opportunities	<p>The proposed scheduling model was developed in close consultation with the National Coordinating Committee on Therapeutic Goods. Widespread consultation on the proposed scheduling model occurred with face-to-face stakeholder meetings in August 2005 and in November 2006 (medicines only) following the release of the relevant draft Australia New Zealand Therapeutic Products Regulatory Scheme legislation.</p> <p>Stakeholder consultation on other aspects of the proposed scheduling model including the <i>Standard for the Uniform Scheduling of Medicines and Poisons</i> and the Scheduling Policy Framework has also occurred.</p>
Expected timetable	It was intended to implement the proposed scheduling arrangements with the commencement of the trans-Tasman therapeutic products regulatory scheme. Due to the decision in July 2007 to postpone negotiations on the establishment of the trans-Tasman therapeutic products regulatory scheme, work to adapt the scheduling framework in Australia is being reviewed.
Contact details	<p>Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au</p>
Date last modified	July 2008

Title	National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2007
Description of issue	The amendments in this Bill are required to implement a 2008-09 Budget measure for cost recovery of processes relating to evaluating and pricing medicines, vaccines and other products for listing on the Pharmaceutical Benefits Scheme and National Immunisation Programme. Fees will be charged to sponsors (generally, the pharmaceutical industry) who bring submissions for listing products to the Pharmaceutical Benefits Advisory Committee for consideration. Details of the cost recovery scheme, including a schedule of fees, will be specified in regulations.
Consultation opportunities	Rounds of consultation with the pharmaceutical industry and other key stakeholders occurred in November 2005, June 2006 and May 2007. Further consultations occurred following the announcement of this measure in the 2008 Budget and will continue prior to implementation. The Department has established an ongoing consultative forum on cost recovery with Medicines Australia and Generic Medicines Industry Australia.
Expected timetable	The Bill is before Parliament. On 18 June 2008, the Senate voted to refer the Bill to the Senate Community Affairs Committee for an inquiry, to report 'not before' 18 August 2008. Commencement of fees is subject to Parliamentary approval.
Contact details	<p>Diana MacDonell Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: diana.macdonell@health.gov.au</p>
Date last modified	3 July 2008

Title	Negotiations with the view to amend the Agreement between the Government of Australia and the Government of New Zealand establishing a System for the Development of Joint Food Standards (the Treaty)
Description of issue	The Review of the Treaty conducted during 2006-07 identified a number of ways to improve the operation or effectiveness of the Treaty. Addressing the identified issues through negotiations with the view to amending the Treaty will further strengthen the Treaty Objectives which are seeking to: <ul style="list-style-type: none"> • reduce unnecessary barriers to trade; • maintain a trans-Tasman system for the development and promulgation of joint food standards; and • share information on matters relating to food.
Consultation opportunities	The Treaty amendment process requires the development of a National Impact Assessment and consultation with industry, State and Territory governments and other stakeholders.
Expected timetable	Given the steps required and subject to the ease of resolution of issues, the Department anticipates that the Treaty negotiation and amendment process will take around 12 months.
Contact details	Catherine Gay Research Policy and Biotechnology Branch Department of Health and Ageing Ph: (03) 9665 8910 Email: catherine.gay@health.gov.au
Date last modified	14 July 2008

Title	Proposed amendments to restrict advertising of tobacco products on the internet
Description of issue	Proposed amendments to the <i>Tobacco Advertising Prohibition Act 1992</i> and the <i>Tobacco Advertising Prohibition Regulations (Statutory Rules 1993 No. 129)</i> to clarify the legislation's intent in respect of advertising on the internet. Amendments will clarify that the prohibition on the advertising of tobacco products applies to advertisements on the internet. These changes will impact upon businesses selling tobacco products over the internet.
Consultation opportunities	There will be opportunity for public comment during the preparation of a Regulation Impact Statement.
Expected timetable	Preparation of a Regulation Impact Statement is estimated to occur in 2009.
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688 Email: penny.marshall@health.gov.au
Date last modified	July 2008

Title	Pathology and Diagnostic Imaging Prohibited Practices Regulations and market value
Description of issue	These Regulations will set out details relating to specific elements of the pathology and diagnostic imaging prohibited practices provisions of the <i>Health Insurance Act 1973</i> resulting from the <i>Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007</i> .
Consultation opportunities	Consultation with key stakeholder groups, including medical colleges and professional associations, to inform the regulation were undertaken from July to October 2007 and from February to July 2008.
Expected timetable	September 2008
Contact details	Hilary Metcalf Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 8657 Email: hilary.metcalf@health.gov.au
Date last modified	9 July 2008

Title	Review of Accreditation – aged care	
Description of Issue	A review of the Accreditation Standards, the process for accreditation and the development of quality indicators for residential aged care homes will be commenced in 2008-09. The review will seek to strengthen current accreditation and monitoring processes and support quality improvements in residential aged care. The review is expected to identify proposed amendments to the Aged Care Principles.	
Consultation opportunities	The Ageing Consultative Committee and the Aged Care Standards and Accreditation Agency Limited will be consulted throughout the review.	
Expected timetable	The review commenced in 2008-09.	
Contact details	Fiona Nicholls Assistant Secretary Quality, Policy and Programs Branch Office of Aged Care Quality and Compliance Ph: (02) 6289 1765 Email: fiona.nicholls@health.gov.au	Teressa Ward Assistant Secretary Compliance Branch Office of Aged Care Quality and Compliance Ph: (02) 6289 1500 Email: teressa.ward@health.gov.au
Date last modified	July 2008	

Title	Strengthening protections for aged care recipients
Description of issue	The Minister for Ageing has announced a range of measures to improve quality of care to protect frail aged Australians. This will include expanding the requirement for aged care staff to undergo police checks and requiring services providing residential care to report to the Department of Health and Ageing when residents go missing.
Consultation opportunities	The Ageing Consultative Committee and key stakeholders will be consulted throughout the process.
Expected timetable	Changes will be implemented during 2008-09.
Contact details	<p> Teresa Ward Assistant Secretary Compliance Branch Office of Aged Care Quality and Compliance Ph: (02) 6289 1500 Email: teressa.ward@health.gov.au </p>
Date last modified	July 2008

Title	Therapeutic Goods Amendment Bill (No. 1) 2008
Description of issue	This bill will implement a scheme that will exempt medical devices from regulatory requirements in Chapter 4 of the <i>Therapeutic Goods Act 1989</i> , including those relating to inclusion in the Australian Register of Therapeutic Goods so that they can be stored and made available urgently in a national emergency. This will reflect the current arrangements applying to therapeutic goods under Chapter 3 of the Act but with some necessary changes for their application to medical devices.
Consultation opportunities	
Expected timetable	Implementation is anticipated in 2009
Contact details	<p> Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au </p>
Date last updated	July 2008

Title	Therapeutic Goods Amendment Bill (No. 2) 2008
Description of issue	<p>The Bill proposes to amend the <i>Therapeutic Goods Act 1989</i> to include the following measures:</p> <ul style="list-style-type: none"> • ensure that the powers to define, and approve the advertising of, restricted representations apply equally to advertisements that require pre-approval and those that do not; • add the European Pharmacopeia (EP) and the United States Pharmacopeia (USP) as default standards in addition to the British Pharmacopeia. This will allow medicines and other therapeutic goods that are not medical devices to meet the requirements of the EP or the USP as alternatives to the requirements of the British Pharmacopeia. • expand what therapeutic goods information can be released under section 61 of the Act • replace the “fit and proper person” test with provisions that permit the Secretary to suspend, cancel or refuse to grant a manufacturing licence or a conformity assessment certificate on specified grounds. The proposed grounds are considerably narrower versions of the matters that must be considered in applying the existing fit and proper person test. • expand the information gathering powers under the Act to allow the Secretary to require holders of manufacturing licences and conformity assessment certificates to provide information relating to their continuing fitness and propriety; • clarify that the Secretary may vary any aspect of a manufacturing licence and enable manufacturers to apply for variations to their licences; and • other consequential and technical changes.
Consultation opportunities	
Expected timetable	Implementation anticipated in 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au
Date last updated	July 2008

Title	Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008
Description of issue	<p>The Australian National Audit Office has raised concerns on the lack of ability of the TGA to review the eligibility of sponsors applying for or who have been granted exemptions from the payment of annual charges because of low volume low value turnover of therapeutic goods. The Australian Government Solicitor's office also advised that there is some doubt as to whether the regulation-making power in the <i>Therapeutic Goods (Charges) Act 1989</i> (TG Charges Act) empowers the Governor-General to make regulations that impose temporal limitations on making an application for a declaration that turnover is of low volume low value. In order to address these issues, the Bill introduces measures to provide for transparency, accountability and clarity in relation to low volume low value exemption from the payment of annual charges. These measures include ensuring that the <i>Therapeutic Goods Act 1989</i> (the TG Act) supports regulations prescribing all the necessary requirements, allowing for the provision of specified evidence to support a persons claim for that exemption, the ability to request additional information from applicants or from persons already granted the exemption, cancelling exemption and requiring payment of the annual charge, and merits review of decisions cancelling or refusing the granting of exemptions.</p> <p>Other measures include:</p> <ul style="list-style-type: none"> • changes to the current legislative arrangements that prescribe when the annual charges are payable. These changes will provide clear legislative backing to current practice and provides administrative efficiency to the TGA and industry. These changes include the setting of a uniform date for the payment of annual charges; • allowing charges to be set at nil rate which will remove any doubt about the validity of current practice; and • other consequential and technical changes <p>This Bill amends both the TG Act and TG Charges Act.</p>
Consultation opportunities	
Expected timetable	It is proposed to commence on 1 July 2009. The Bill was introduced in the House of Representatives on 18 June 2008 and is currently under consideration.
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Email: marlene.keese@tga.gov.au
Date last modified	July 2008